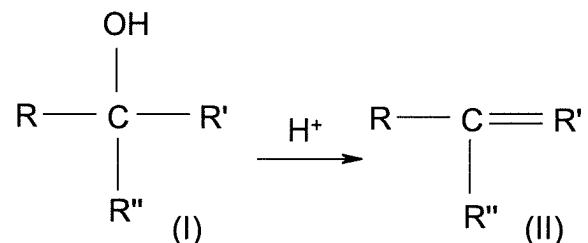


### REMARKS

Currently, claims 60-82, including independent claim 60, are pending in the present application. Independent claim 60, for instance, is directed to a kit for detecting *Helicobacter pylori*. The kit comprises a breath testing device comprising a visual indicating agent that is color sensitive to the ammonia and a breath collecting device. The visual indicating agent contains Michler's hydrol. As is well known in the art, Michler's hydrol has the following general formula (I) or (II):



R is (CH<sub>3</sub>)<sub>2</sub>NC<sub>6</sub>H<sub>5</sub>; R' is (CH<sub>3</sub>)<sub>2</sub>NC<sub>6</sub>H<sub>5</sub>; and R'' is H.<sup>1</sup>

In the Office Action, previous dependent claim 61 (now incorporated into independent claim 60) was rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent Application Pub. No. 2004/0077093 to Pan in view of U.S. Patent Application Pub. No. 2003/0211618 to Patel. Pan is directed to method for detecting the presence of a bacteria in the gastrointestinal tract of a subject. The method comprises delivering a source of urea to the gastrointestinal tract of the subject, obtaining a fluid sample from the subject after the delivery of the urea source, contacting the fluid sample with a sensor, and optically detecting a color change in the

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<sup>1</sup> The Examiner objected to this formula in the Office Action because it "redefined" R, R', and R'' from the original specification. Although this objection is now moot in light of the amendments set forth herein, Applicants respectfully submit that the formula is fully supported by the original specification. For example, the specification shows the structure of Michler's hydrol at p. 5, ll. 5-15. The R, R', and R'' groups were simply amended to reflect this formula and to correct an obvious typographic error.

sensor that is indicative of the presence of ammonia in the fluid sample. The sensor includes a dye having the capacity to become deprotonated and undergo a color change in the presence of ammonia. The contact conditions are controlled so that the sensor responds to the presence of ammonia in the fluid sample, but not to the pH of the fluid sample by undergoing an optically discernible color change. Suitable pH sensitive dyes are said to include bromophenol blue, bromothymol blue, methyl yellow, methyl orange, 2,4-dinitrophenol, 2,6-dinitrophenol, phenol red, and cresol red. Nevertheless, as acknowledged by the Examiner, Pan fails to disclose one or more aspects of the claimed kit. For instance, Pan fails to disclose a visual indicating agent that contains Michler's hydrol as set forth in independent claim 60.

Nevertheless, Patel was combined with Pan in the Office Action in an attempt to render obvious dependent claim 61. Patel is directed to a color change steam indicator. In its "Brief Description of the Prior Art", Patel cursorily mentions that solvatochromatic dyes have been used to change color in the presence of solvents. One of the dyes mentioned is "Michler's ketone", which is 4,4'-bis(N,N-dimethylamino)benzophenone – the carbinol base form of "Michler's hydrol." Based on this recitation, the Office Action indicates that it would have been obvious to modify the kit of Pan with the "ammonia indicator dye . . . of Patel because both Pan and Patel are directed to detection of ammonia." (p. 11). Applicants respectfully disagree. Patel is directed to the detection of **water vapor and steam** – not ammonia. The only mention of "ammonia" in Patel relates to *binders* in which the steam indicators can be dispersed. More specifically, Patel suggests that acrylic resins may be employed as a *binder* that are "emulsifiable through neutralization with basic compounds, such as ammonia and amines." ¶ [0082].

Clearly, one of ordinary skill in the art would not have found it obvious to selectively choose a solvatochromatic dye from a reference relating to *steam* detection (Patel) for use in a reference relating to *ammonia* detection (Pan).

In addition the rejection noted above, the Office Action also objected to the specification based on Applicants' previous amendment to recite that a "source of urea." Although this phrase has been removed from the specification, Applicants respectfully submits that the original specification fully supports this phrase. As one of ordinary skill in the art would readily recognize, the specification's reference to "urea" refers to a source of urea. Even Pan, which was cited by the Examiner in the Office Action, refers to the well known use of a "source of urea" (e.g., urea per se or it may be a derivative of urea) for delivery to the gastrointestinal tract of a subject. Applicants submit that the specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

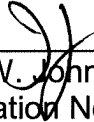
As a final note, claims 60-81 were rejected in the Office Action under the judicially created doctrine of obviousness-type double patenting in view of copending Application No. 10/687,270. To the extent necessary, Applicants agree to consider the submission of a terminal disclaimer to obviate this rejection at such time that the claims are otherwise in condition for allowance.

Applicants respectfully submit that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Portner is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this response.

Appl. No. 10/687,327  
Amdt. dated Jul. 9, 2007  
Reply to Office Action of Mar. 8, 2007

Respectfully requested,

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